

## **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **I. DISPOSITION OF THE CLAIMS**

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 1 – 3, 49, and 57 are amended. Claims 52 – 56, 61 – 63, 95 – 96, and 98 have been canceled. Claims 4 – 47 were previously canceled. Claims 64-93 remain withdrawn. Thus, claims 1 – 3, 48 – 51, 57 – 60, 94, and 97 are under examination.

No new matter has been added. The amendments to claims 1 and 57 introducing an ID50 threshold for FcγRIIIA binding are supported by the specification, page 11, line 23 to page 12, line 18. This cited passage in the specification also describes a specific assay.

### **II. OBJECTIONS**

Applicants have obviated the objections by amendment, as explained below.

#### **A. Specification (Title)**

In response to the Office requirement to replace the title (Office Action, page 3, paragraph 4), Applicants have amended the title to “Preparation Of Human, Humanized Or Chimæric Antibodies Or Polypeptides Having Different Binding Profiles To Fcγ Receptors”.

#### **B. Claim 95**

The Office objected to claim 95 as duplicative of claim 94 (Office Action, page 3, paragraph 5). Claim 95 has been canceled.

### **III. CLAIM REJECTION UNDER 35 U.S.C. § 112**

Claims 1 – 3, 48 – 51, 57 – 60, 94, and 97 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants disagree with this ground of rejection.

To further prosecution, Applicants have obviated this ground of rejection by amendment. Claims 1 and 57 now refer to an ID50 threshold for Fcγ<sub>3</sub> binding. The specification, page 12, lines 14-18, discloses the ID50 threshold and a specific assay for determining ID50 values.

Accordingly, Applicants request withdrawal of this ground of rejection.

### **IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

Applicants have obviated by amendment the anticipation rejections over Shields and Shinkawa, as explained below.

#### **A. Shields**

Claims 1-3, 48 and 49 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Shields et al., Journal of Biological Chemistry, Vol. 277, No. 30, 2002, pgs. 26733-26740 (“Shields”). Applicants disagree with this ground of rejection.

To further prosecution, independent claim 1 has been amended to omit the embodiments wherein the “selecting antibodies or polypeptides” step includes selecting antibodies or polypeptides which “i. bind to Fcγ<sub>3</sub>, Fcγ<sub>2</sub> and Fcγ<sub>1</sub>” or “iii. do not bind or bind only weakly to Fcγ<sub>3</sub>, Fcγ<sub>2</sub> and Fcγ<sub>1</sub>”.

The change to claim 1 reflects the antibody binding scope of independent claim 57, which the Office did not include in the anticipation rejections.

The amendment retains the embodiments wherein the “selecting antibodies or polypeptides” step includes selecting antibodies or polypeptides which “bind to Fcγ<sub>2</sub> and Fcγ<sub>1</sub> but do not bind to Fcγ<sub>3</sub> or bind to Fcγ<sub>3</sub> with an ID50 superior or equal to 0.2 microM”.

The Office's rejection over Shields is based on disclosures in each reference of antibodies that bind to FcgammaRIIIA. The Office's rejection over Shields is based on the Shields disclosure of "selecting antibodies which bind to all three types of receptors" (Office Action, page 4, penultimate paragraph). Shields could anticipate claim 1, because Shields fails to disclose "selecting antibodies or polypeptides which "bind to FcgammaRIIA and FcgammaRIIB but do not bind to FcgammaRIIIA or bind to FcgammaRIIIA with an ID50 superior or equal to 0.2 microM".

Applicants note that the Office did not reject independent claim 57 and its dependent claims 58 – 60 and 97 for anticipation over Shields. Claim 57 recites identical language regarding binding to FcgammaRIIIA. Applicants amended this limitation in claims 1 and 57 (to recite a specific ID50) in response to the indefiniteness rejection.

Accordingly, Applicants request withdrawal of the anticipation rejection over Shields.

#### **B. Shinkawa**

Claims 52-55 and 96 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Shinkawa et al., Journal of Biological Chemistry, Vol. 278, No. 5, 2003, pp. 3466-3473 ("Shinkawa"). Applicants disagree with this ground of rejection.

To further prosecution, Applicants have obviated the anticipation rejection over Shinkawa by canceling claims 52 – 55 and 96. Accordingly, Applicants request withdrawal of the anticipation rejection over Shields.

Applicants request that the Office issue a Form PTO-892 listing Shinkawa with the next official action. The Office asserted that Shinkwa is "of record" (Office Action, page 5, line 2). Applicants found no record of Shinkawa in the prosecution history, neither in Applicants' SB/08 form filed with an IDS, nor in the Office's "Notice of References Cited" (Form PTO-892) issued with the outstanding Office Action.

#### **V. CLAIM REJECTION UNDER 35 U.S.C. § 103**

Claims 50 – 51 and 94 stand rejected under 35 U.S.C. § 103(a) as being obvious over Shields. Applicants respectfully traverse this ground of rejection.

To further prosecution, Applicants have amended the claims to obviate the anticipation rejection over Shields. The Office relies on anticipation of base claim 1 to construct the obviousness rejection (Office Action, page 6, lines 12 – 15):

The teachings of Shields et al. have been discussed above, and include a method of preparation of a human antibody by expressing a human IgG in a CHO derived cell line, testing the binding of said antibodies to FcγRIIA, FcγRIIA [sic; FcγRIIIA] and FcγRIIB, and selecting antibodies which bind to all three types of receptors.

As noted above in discussing anticipation, Shields does not disclose the claimed selecting for antibodies with little or no binding to FcγRIIIA.

Applicants note that the Office did not reject independent claim 57 and its dependent claims 58 – 60 and 97 as obvious over Shields.

Accordingly, Applicants request withdrawal of the obviousness rejection.

## **VI. DOUBLE PATENTING REJECTION**

Claims 1-3, 48-55, 57-60 and 94-97 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 6-10 of copending Application 10,257,44; claim 19 of copending Application 11/517,525 and claim 33 of Application 10/527,664, published as U.S. Patent Publication No. 2003/0175969, 2007/0009522 and 2006/0127392, respectively.

Applicants request that this rejection be held in abeyance pending indication of allowable subject matter.

## **CONCLUSION**

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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